UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,145	09/18/2006	Yuichi Oku	OKUY3002/GAL	8771

23364 7590 07/22/2010

BACON & THOMAS, PLLC
625 SLATERS LANE
FOURTH FLOOR
ALEXANDRIA, VA 22314-1176

EXAMINER	
LUNDGREN, JEFFREY S	

ART UNIT	PAPER NUMBER
1639	

MAIL DATE	DELIVERY MODE
07/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

JUL 22 2010

George A. Loud
BACON & THOMAS, PLLC
625 SLATERS LANE
FOURTH FLOOR
ALEXANDRIA VA 22314-1176

In re Application of :
OKU et al. :
Serial No.: 10/593,145 : PETITION DECISION
Filed: 18 September 2006 :
Attorney Docket No.: OKUY3002/GAL :

This is in response to the petition under 37 CFR 1.144, filed 11 January 2010, requesting the Director to reconsider the lack of unity requirement. The delay in acting upon this petition is regretted.

BACKGROUND

This application is a national stage filing under 35 USC 371 of PCT/JP2005/4953 and, as such, is eligible for PCT unity of invention practice.

On 25 March 2009, the examiner mailed a restriction requirement in which the claims were divided into 40 groups. The examiner further required an election of species. The examiner justified that the claims lacked unity of invention in view of the teachings of Sharat et al.

On 25 March 2009, applicants responded by electing Group XXXX, claims 52 and 54 with traverse. Along with this election, applicants filed an amended claim set which cancelled claim 54.

On 13 November 2009, the examiner prepared a non-final Office action.

The examiner indicated that the election was made without traverse. Claims 1-51 were withdrawn from consideration. Claim 52 was rejected under 35 USC 112, second paragraph as being indefinite. Claim 52 was rejected under 35 USC 103(a) as being unpatentable over Hu in view of Wilding. The prior art reference of Sharat, which was used to initially show unity of lacking, was not applied to claim 52.

On 11 January 2010, applicants filed this petition to request that the Office reconsider the lack of unity determination.

On 16 February 2010, applicants filed a response to the Office action along with amended claims.

On 22 March 2010, applicants filed a supplemental response.

DISCUSSION

The petition and file history have been carefully considered.

Before addressing the merits of the petition, the timeliness of the petition will be considered. 37 CFR 1.144 requires that before a petition can be filed, applicants must have requested reconsideration of a restriction requirement.

After a final requirement for restriction, the applicant, in addition to making any reply due on the remainder of the action, may petition the Director to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested (see § 1.181).

In the Office action mailed 13 November 2009, the examiner stated that the election was made without traverse. This is incorrect. In the response filed on 25 June 2009, applicant elected Group XXXX with traverse. See page 38, second full paragraph of the response.

> Hiowever, the requirement for election is respectfully traversed. As the examiner recognizes, the captioned application is a U.S. National Phase of a PCT application and as such, the rules pertaining to restriction in U.S. domestic applications do not apply and the test is that of "Unity of Invention" under PCT rules 3.1 and 3.2. It is respectfully submitted that the Examiner has not identified what applicants regard as the "common technical feature." It is further submitted that the test for unity of invention is satisfied here in that all of the claims recite a "common technical feature" as a combination of immunoreactive reagents for assay of an antigen, including a first nucleic acid fixed, in a "capturing zone", to one of the first and second members **and an antibody.** WO01/61041 has different reagents dictated by its different use, i.e. to screen genomes for certain traits. See, for example page 1, lines 10-19.
>
> Accordingly, given recognition of the "common technical feature" described above, it is respectfully requested that the requirement for restriction be withdrawn.

The examiner failed to acknowledge or consider this traversal. Because applicants elected with traverse, the petition is considered timely filed after a request for reconsideration.

Next, in the lack of unity determination, the examiner has failed to identify a technical feature for each group. For example, each of Groups I to X is identified as being "drawn to an analytical kit" without specifying the distinguishing features of each kit. This is counter to MPEP 814, which states:

The examiner must provide a clear and detailed record of the restriction requirement to provide a clear demarcation between restricted inventions so that it can be determined whether inventions claimed in a continuing application are consonant with the restriction requirement and therefore subject to the prohibition against double patenting rejections under 35 U.S.C. 121. Geneva Pharms. Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1381, 68 USPQ2d 1865, 1871 (Fed. Cir. 2003). See also MPEP § 804.01.

Applicants have claimed a product, a method of making the product and a method of using the product. The International Search and Examination Guidelines provide Example 1 to address this situation.

> "Claims in Different Categories
>
> 10.21 Example 1
>
> Claim 1: A method of manufacturing chemical substance X.
>
> Claim 2: Substance X.
>
> Claim 3: The (method of) use of substance X as an insecticide.
>
> Unity exists between claims 1, 2 and 3. The special technical feature common to all the claims is substance X. However, if substance X is known in the art, unity would be lacking because there would not be a special technical feature common to all the claims."

In example, 1, the same or corresponding technical feature is "Substance X'. In the instant case, the same or corresponding technical features are identified as the combination of an analytical device comprising a device comprising a first nucleic acid and a reagent containing a conjugate of a second nucleic acid and a ligand that binds to an antigen. In some claims, the ligand may be an antibody.

This technical feature is required by all of independent claims 1-10, 18-19, drawn to the device, all of the independent claims 24-29, directed to a method of using the device and all of independent claim 51 and 52, drawn to a method of making the device. The various dependent claims merely provide additional limitations. This analysis is consistent with ISPE Guidelines which state

> "10.06 Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent"

> claim is meant a claim which contains all the features of one or more other claims and contains a reference, preferably at the beginning, to the other claim or claims and then states the additional features claimed (Rule 6.4). The examiner should bear in mind that a claim may also contain a reference to another claim even if it is not a dependent claim as defined in Rule 6.4. One example of this is a claim referring to a claim of a different category (for example, "Apparatus for carrying out the process of Claim 1 ...," or "Process for the manufacture of the product of Claim 1 ...")."

Paragraph 10.02 of the International Search and Examination Guidelines sets forth the following guidance on unity of invention:

> Whether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," is considered with respect to novelty and inventive step.

Here, the examiner has asserted that the same or corresponding technical feature was a device comprising a first member covering a groove 1 um to 5mm wide and 1 um to 750 um deep.

The petition correctly argues that the Sharat reference fails to teach the technical feature of an antibody and a nucleic acid antigen, as required by claim 1, for example. However, in this situation, if the examiner can provide an additional reference, or combinations of references to demonstrate that the same or corresponding technical feature does not make a contribution over the prior art, then unity of invention would be lacking a posteriori.

In the non-final Office action dated 13 November 2009, the examiner indicated that claim 52 was rejected under 35 USC 103(a) as being unpatentable over Hu et al in view of Wilding et al. Applicant argues that Hu et al also fail to teach a conjugate of an antibody and a nucleic acid.

This argument is persuasive. The Hu reference, directed to a monoclonal antibody array, mentions nucleic acids in two places. Paragraph 0018, describes that the antigen may be a polynucleotide, oligonucleotide or a nucleic acid. Paragraph 19 explains that the techniques for constructing arrays for polynucleotides are instructive to constructing arrays for monoclonal antibodies. Neither of these section teaches a conjugate of a ligand or an antibody to a nucleic acid as required by claim 1, step (ii), for example. For this reason, the examiner has not provided evidence that the shared or corresponding technical feature does not make a contribution over the prior art.

Unity of invention is present amongst the product, method of making it and method of using it. For this reason, the lack of unity determination is improper and the first Office action on the merits incomplete for not addressing the withdrawn claims.

DECISION

The petition is **GRANTED** as follows:

Applicant's election with traverse is acknowledged. That traversal is sufficient to permit applicants to petition and request further reconsideration of the restriction requirement.

The lack of unity determination mailed 25 March 2009 is withdrawn.

The Office action mailed 13 November 2009 is incomplete for not addressing the withdrawn claims.

The application will be forwarded to the examiner for preparation of an Office action consistent with this decision.

Should there be any questions about this decision, please contact Quality Assurance Specialist Julie Burke, by letter addressed to Director, Technology Center 1600, at the address listed above, or by telephone at 571-272-0512 or by facsimile sent to the general Office facsimile number, 571-273-8300.

JMStone

Jacqueline Stone
Director, Technology Center 1600